



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development

New proposed collection; comment request

Stress and Cortisol Measurement for the National Children's Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: *Title:* Stress and Cortisol Measurement Substudy for the National Children's Study (NCS). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The Children's Health Act of 2000 (Public Law 106-310) states:

(a) PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

(c) REQUIREMENT.—The study under subsection (b) shall—

(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial

environmental influences on children's well-being;
(2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and
(3) consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the Stress and Cortisol Measurement Substudy will develop an optimized, item-reduced measure of self-reported stress that is supported empirically through convergent validity analysis of stress biomarkers. Specifically, key moderators of stress biomarkers will be evaluated to inform the efficiency and quality of measurements during pregnancy. Development of a scientifically robust maternal stress measure would measure chronic stress more efficiently, would not require biospecimen collection and biomarker analyses, and would thereby reduce participant burden and NCS Vanguard (Pilot) and NCS Main Study costs. With this information collection request, the NCS seeks to obtain OMB's clearance to conduct a substudy aimed at developing a validated questionnaire that will reflect specific biological and physiological measures of maternal stress.

BACKGROUND: The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines "environment" broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. By studying children through their different phases of growth and development, researchers will be better able to understand the role these factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible. The National Children's Study is led by a consortium of federal partners: the U.S. Department of Health and Human Services (<http://www.hhs.gov/>) (including the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (<http://www.nichd.nih.gov/>) and the National Institute of Environmental Health Sciences (<http://www.niehs.nih.gov/>) of the National Institutes of Health (<http://www.nih.gov/>) and the Centers for Disease Control and Prevention (<http://www.cdc.gov/>)), and the U.S. Environmental Protection Agency (<http://www.epa.gov/>).

To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the Vanguard Study. The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study procedures, and outcome assessments that are to be used in the NCS Main Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study.

In this information collection request, the NCS requests approval from OMB to perform a multi-center substudy, called the Stress and Cortisol Measurement Substudy. This substudy aims to determine the most reliable, acceptable, and cost-efficient approach for assessing maternal stress. Maternal stress is of particular interest to the NCS due to studies that have shown an association between maternal stress and negative health outcomes, including preterm birth which is one of the most important problems in maternal-child health in the US. Stress factors are also more prevalent in the population of socio-demographically disadvantaged women who are at an increased risk for preterm birth. Maternal stress is associated with additional health outcomes, such as still-birth, low birth weight, problems in offspring brain function and behavior (including lower IQ and impaired executive function), immune-related problems such as allergies and asthma, congenital malformations, infections, and numerous disorders of organ systems.

Development of a scientifically robust and validated questionnaire to reflect specific physiological measures of stress would allow us to measure chronic stress more efficiently, would not require biospecimen collection and biomarker analyses, and would thereby reduce participant burden and Study costs. To develop this instrument, the NCS will collect several types of information from substudy participants through medical record abstraction, questionnaires (a series of validated stress measures), physiological measures (heart rate and self-reported stress), and several types of biospecimens.

Frequency of Response: Annual [As needed].

Affected Public: Pregnant women and their children.

Type of Respondents: Pregnant women who are not geographically eligible to enroll in the NCS Vanguard Study.

Annual reporting burden: See Table 1. The annualized cost to respondents is estimated at: \$74,677 (based on \$10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Table 1. Estimated Annual Reporting Burden Summary, Stress and Cortisol Measurements					
Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours
Screening	Members of NCS target population (not NCS participants)	2,100	1	0.08	175
Consent	Members of NCS target population (not NCS participants)	700	1	0.17	117
Saliva Self-Collection Demonstration	Members of NCS target population (not NCS participants)	700	1	0.25	175
Urine Self-Collection Instructions	Members of NCS target population (not NCS participants)	700	1	0.08	58
Ecological Momentary Assessment Training	Members of NCS target population (not NCS participants)	700	1	0.50	350
Visit 1 Stress Questionnaire	Members of NCS target population (not NCS participants)	700	1	1.00	700

Table 1. Estimated Annual Reporting Burden Summary, Stress and Cortisol Measurements					
	participants)				
Adult Blood	Members of NCS target population (not NCS participants)	700	2	0.50	700
Adult Urine	Members of NCS target population (not NCS participants)	700	1	0.25	175
Adult Hair	Members of NCS target population (not NCS participants)	700	2	0.25	350
Adult Saliva	Members of NCS target population (not NCS participants)	700	28	0.05	980
Demographic and Health Interview	Members of NCS target population (not NCS participants)	700	1	1.00	700
Participant Contact Information Sheet	Members of NCS target population (not NCS participants)	700	1	0.08	58
Take-Home Questionnaire	Members of NCS target population (not NCS participants)	700	1	0.50	350
Time Diary	Members of NCS target population (not NCS participants)	700	72	0.03	1,680

Table 1. Estimated Annual Reporting Burden Summary, Stress and Cortisol Measurements					
Heart Monitoring	Members of NCS target population (not NCS participants)	700	1	0.03	23
Visit 2 Stress Questionnaire	Members of NCS target population (not NCS participants)	700	1	0.75	525
Stressful Life Events Schedule Checklist	Members of NCS target population (not NCS participants)	700	1	0.50	350
Total		700			7,467

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland, 20892, or call non-toll free number (301) 496-1877 or E-mail your request, including your address to glavins@mail.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: February 10, 2012

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[FR Doc. 2012-3809 Filed 02/16/2012 at 8:45 am; Publication Date: 02/17/2012]